LORATADINE- loratadine tablet
A-S Medication Solutions

Drug Facts

Active Ingredient (in each tablet)

Loratadine, USP 10 mg

Purpose

Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

liver or kidney disease.Your doctor should determine if you need a different dose.

When using this product

do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor

if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 6 years and over	1 tablet daily; not more than 1 tablet in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other Information

- Safety sealed: do not use if the imprinted bottle seal is open or torn (for bottle only).
- Safety sealed: do not use if open or torn (for blister package only).
- Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature).

Inactive Ingredients

Lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

Questions or comments?

1-800-206-7821

 I10-2015M

Manufactured for: Northstar Rx LLC

Memphis, TN 38141.

Manufactured by: Sandoz Inc.

Princeton, NJ 08540.

HOW SUPPLIED

Product: 50090-3620

NDC: 50090-3620-0 10 TABLET in a BOTTLE

NDC: 50090-3620-3 15 TABLET in a BOTTLE, PLASTIC

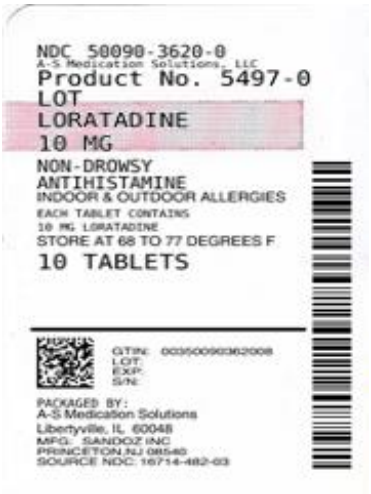
NDC: 50090-3620-4 30 TABLET in a BOTTLE, PLASTIC

NDC: 50090-3620-5 90 TABLET in a BOTTLE, PLASTIC

NDC: 50090-3620-1 20 TABLET in a BOTTLE, PLASTIC

NDC: 50090-3620-6 7 TABLET in a BOTTLE, PLASTIC

Loratadine



LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-3620(NDC:16714-482)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE (white to off white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	GG296
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50090-3620-0	10 in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2018	
2	NDC:50090-3620-3	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2016	
3	NDC:50090-3620-4	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2016	
4	NDC:50090-3620-5	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2016	
5	NDC:50090-3620-1	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2016	
6	NDC:50090-3620-6	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075209	02/01/2016	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3620) , REPACK(50090-3620)

Revised: 4/2019 A-S Medication Solutions